

510(K) Summary

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K962717

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Device Names: 6 Fr Guiding Catheter with Phosphorylcholine ("PC")
Polymer Coating
7 Fr Guiding Catheter with PC Polymer Coating
8 Fr Guiding Catheter with PC Polymer Coating

Common Name: Guiding Catheter

Classification Name: Percutaneous Catheter (21 CFR 870.1250)

Predicate Devices: Cordis Corporation 6 Fr Brite Tip® Guiding Catheter /
Cordis Corporation 8 Fr Brite Tip® Guiding Catheter

Device Description:

The 6 Fr, 7 Fr, and 8 Fr Guiding Catheters with PC Polymer Coating have shaft nominal outside diameters of 0.079", 0.092", and 0.104" with nominal inside diameters of 0.064", 0.075", and 0.087", respectively. The guiding catheters are available in lengths of 65 cm, 85 cm, 100 cm, and 110 cm. Distal side holes and different curve styles are available. The inner and outer surfaces of the guiding catheter are coated with a hydrophilic polymer. The catheter hub is disk shaped and injection molded onto the shaft. The shaft is an extruded thermoplastic with an embedded stainless steel braided wire extending from the hub to the radiopaque tip. A hub-to-shaft kink protector is included. The tip is made of a low durometer radiopaque thermoplastic and is heat welded to the end of the catheter shaft. The guiding catheters are packaged in Tyvek/Mylar heat sealed sterilization pouches and gas sterilized by ethylene oxide.

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Intended Use:

The Guiding Catheters with PC Polymer Coating are indicated to aid the percutaneous placement of guide wires, balloon dilatation catheters, and other devices required for peripheral and coronary artery transcatheter diagnosis and therapy. The guiding catheters are not intended for use in the cerebral vasculature.

Comparison of Technological Characteristics:

The Guiding Catheters with PC Polymer Coating have similar technological characteristics as the predicate devices. The respective guiding catheters have injection molded luer hubs designed to allow device torqueing, kink protection sheaths, thermoplastic catheter shafts with embedded braided stainless steel wire, and have radiopaque tips. Guiding catheter lumen diameters are similar for each size catheter. Curve styles of the guiding catheters with PC polymer coating are similar to those marketed for the predicate devices. Both guiding catheters are available with optional side holes. The predicate guiding catheters have an inner 0.0015" Teflon liner and are not coated on the outside. The lumen and outside wall of the BCP guiding catheters are coated with PC polymer. Predicate device tips are solvent bonded to the catheter shafts; the BCP catheter tips are heat welded to the shafts.

Packaging and Sterilization

The BCP and predicate guiding catheters are individually packaged in a Tyvek/Mylar heat sealed gas sterilization pouches and sterilized by ethylene oxide gas. The sterile shelf life of the BCP guiding catheters is two years; the shelf life of the predicate devices is three years.

Safety and Effectiveness:

In vitro performance testing was conducted to determine the safety and effectiveness of the BCP guiding catheters in comparison to the predicate devices. The 6 Fr and 8 Fr guiding catheters of each manufacturer were tested. The PC-coated guiding catheters were found to have adequate tensile strength at the hub-to-shaft and tip-to-shaft joints. Additional tests demonstrated acceptable shaft wall strength at pressures of 500 psi. The biocompatibility of the BCP guiding catheter was tested and the results showed the device to be non-toxic, non-irritating, non-pyrogenic, and blood compatible. The BCP guiding catheters are biocompatible for short term use in the vascular system.

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Based on the indications for use, design and construction, and results of the bench and biocompatibility testing, the BCP Guiding Catheters with PC Polymer Coating are equivalent to the predicate device.

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